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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,740	04/19/2007	Hikaru Matsuda	49288.2900	8359

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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
09/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,740	MATSUDA ET AL.	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-115* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction Requirement

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-44, 77, 99, and 108-115 drawn to a decellularized tissue, a tissue graft comprising a decellularized tissue, pharmaceutical compositions comprising a decellularized tissue, and use of a decellularized tissue to produce said pharmaceutical compositions comprising said decellularized tissue.

Group 2, claim(s) 45-76, drawn to a method of producing a decellularized tissue.

Group 3, claim(s) 78-98, drawn to a method of tissue regeneration and methods of producing a tissue graft using a decellularized tissue.

Requirement for Unity of Invention

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories ('groups'):

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Where such a combination of categories of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

In the instant application there are claims directed to multiple categories of invention, specifically to a product (a decellularized tissue) (Group 1), a process specially adapted for the manufacture of said product (Group 2), and a use of said product (Group 3). This combination of categories (groups) is provided for in 37 CFR 1.475(b) (combination (3)) and thus the groups of inventions do not lack unity *a priori*.

However, the groups of inventions are found to lack unity of invention *a posteriori* because the groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1

because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups 1-3 lack unity of invention because even though the inventions of these groups require the technical feature of **a decellularized tissue which has been subjected to a radical reaction**, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of **Wolfinbarger, Jr et al (US Patent 6,734,018)**. Wolfinbarger, Jr et al disclose production of acellular (decellularized) tissues, during the decellularization process the tissues may be treated with decontaminating agents, of which hydrogen peroxide (a free radical source) is a disclosed example (See Wolfinbarger, Jr et al, col. 8, ln 7-27 & col. 5, ln 11-23); thus Wolfinbarger, Jr et al disclose a decellularized tissue which has been treated with a free radical. Alternatively, Wolfinbarger, Jr et al disclose the tissue may be terminally sterilized by gamma irradiation (See Wolfinbarger, Jr et al, col. 9, ln 46-52); thus Wolfinbarger, Jr, et al disclose a decellularized tissue which has been exposed to gamma irradiation. Both exposure to hydrogen peroxide and gamma irradiation satisfy the claim limitation of 'radical reaction' (See claims 9 and 11) and thus the shared technical feature of a decellularized tissue which has been subjected to a radical reaction does not present a contribution over the prior art, so unity of invention is lacking.

Election of Species

This application contains claims directed to more than one species of the generic invention:

1. Decellularized tissues subjected to different radical reactions, the species are as follows:

a) decellularized tissues subjected to exposure to a free radical [source] (claims 9, 11, 46, 48, 79, 93, 101, 109)

b) decellularized tissue subjected to gamma-ray irradiation (claims 11-13, 48-50, 75)

c) decellularized tissue subjected to ultraviolet irradiation (claims 11, 48)

d) decellularized tissue subjected to exposure to ultrasonication (claims 11, 48)

d) decellularized tissue subjected to electron beam irradiation (claims 11, 48)

e) decellularized tissues subjected to x-ray irradiation (claims 11, 48)

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. because the species do not share the same or corresponding technical feature, therefore unity of invention is lacking *a priori.* Specifically, because each of the species of decellularized tissues require subjection to distinct radical reactions, there is no shared feature between the different species. Currently claims 1, 45, 78, 92, 100, & 108 are generic.

2. Type of decellularized tissue, the species are as follows:

a') luminal tissue (claims 31, 59)

b') blood vessel tissue (claims 32, 60, 91, 95, 105, 110)

c') blood vessel-like tissue (claims 32, 60, 91, 95, 105, 110)

d') cardiac valves (claims 32, 60, 91, 95, 105, 110)

e') pericardia (claims 32, 60, 91, 95, 105, 110)

f') dura mater (claims 32, 60, 91, 95, 105, 110)

g') cornea (claims 32, 60, 91, 95, 105, 110)

h') bone tissue (claims 32, 60, 91, 95, 105, 110)

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. because the species do not share a corresponding technical feature, therefore unity of invention is lacking *a priori.* Specifically, because each of the species of decellularized tissues is a distinct species of tissue, there is no common shared feature between the various tissue types. Claims 1, 45, 78, 92, 100 and 108 are generic.

3. A physiologically active substance capable of including cell differentiation provided to the organism receiving the decellularized tissue, the species are as follows:

a") a nucleic acid (claims 88, 89)

b") HGF (a polypeptide) (claims 88-90)

c") VEGF (a polypeptide) (claims 88-90)

d") FGF (a polypeptide) (claims 88-90)

e") IGF (a polypeptide (claims 88-90)

f") PDGF (a polypeptide (claims 88-90)

g") EGF (a polypeptide) (claims 88-90)

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. because the species do not share a corresponding technical feature, therefore unity of invention is lacking *a priori*. Specifically, because each of the species of physiologically active substances are unique, there is no shared common technical feature. Claim 87 is generic.

Applicant is required, in reply to this action, to elect a single species FROM EACH OF THE ABOVE THREE (3) GROUPS to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1651